

Miles

DEC 29 1995

8381 '97 AUG 12 AIO :04

Mr. Ernest Fleming  
President  
Global Marketing International  
397 Dal Rich Village  
Suite 101  
Richardson, Texas 75080

Dear Mr. Fleming:

This is in response to your letter of September 11, 1995 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement in the labeling of the product "Soy Life."

As a result of numerous studies, evidence is mounting that soybeans may inhibit tumor growth. Genistein, an Isoflavone found chiefly in soybeans, has been identified as an angiogenesis [sic] blocker. Angiogenesis [sic] is the process by which new blood vessels grow and nourish malignant tumors. By blocking angiogenesis, isoflavones may inhibit tumors.

We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of disease. The statement that you are making for "Soy Life," however, suggests that this product is in fact intended for one of these purposes in that it claims to inhibit tumor growth and block the growth and nourishment of malignant tumors. Therefore, this claim does not qualify as a section 403(r)(6) claim. Use of this claim on the label or in the labeling of your product is likely to subject it to regulation under the drug provisions of the act.

If you intend to make claims of this nature, you should immediately contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Sincerely yours,

Elizabeth A. Yetley, Ph.D., R.D.  
Director  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 49

Page 2 - Mr. Ernest Fleming

cc:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Compliance, HFD-300  
7520 Standish Place  
Rockville, Maryland 20855-2737

Food and Drug Administration  
Dallas District Office  
Office of Compliance, HFR-SW140  
3310 Live Oak Street  
Dallas, Texas 75204

Food and Drug Administration  
Office of the Associate Commissioner for Regulatory Affairs  
Office of Enforcement, HFC-200  
5600 Fishers Lane  
Rockville, Maryland 20857

cc:

HFA-224 (w/incoming)  
HFS-22 (CCO, KCarson)  
HFS-456 (r/f)  
HFS-450 (r/f)  
HFS-456 (Miles)  
HFD-304 (Aronson)  
HFS-600 (Reynolds)

Drugs - File Name



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NUTRITIONALS, HFS-450  
SEP 18 1995

September 11, 1995

Elizabeth A. Yetley PH.D  
Acting Director  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S. W. (HFS-450)  
Washington, D. C. 20204

Re: Notice of Statements of Nutritional Support

Dear Dr. Yetley,

Global Marketing International has enclosed an information statement after researching the benefits of Soy Protein Isolates. This statement will be included on the label of our product named "Soy Life" a Soy Protein Isolate based dietary supplement product.

The statement "As a result of numerous studies, evidence is mounting that soybeans may inhibit tumor growth. Genistein, an Isoflavone found chiefly in soybeans, has been identified as an angiogenesis blocker. Angiogenesis is the process by which new blood vessels grow and nourish malignant tumors. By blocking angiogenesis, isoflavones may inhibit tumors."

This statement is submitted pursuant to section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act. This statement will include, prominently displayed and in bold face type the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This correspondence is to serve as notification to the FDA on behalf of Global Marketing International, that the dietary supplement product, Soy Life, is being marketed with a statement of nutritional support on its label or in its labeling.

If you have any questions, please call (214) 520-4039. Thank you in advance for your prompt reply.

Best Regards,

*Ernest Fleming*  
Ernest Fleming  
President

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